implied that it might be taken as frequently as desired with safety; (2) in that it was for use by man and contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found by the Federal Security Administrator, after investigation, to be, and by regulations designated as, habit-forming, and (a) its label failed to bear the statement: "Warning—May be habit forming" in juxtaposition with the name and quantity or proportion of such derivative of barbituric acid, and (b) its label failed to bear, as such regulations specify, the name and quantity or proportion of phenobarbital and the statement: "Warning—May be habit forming," immediately following, without intervening written, printed, or graphic matter, the name by which such drug was titled.

On August 17, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

905. Misbranding of Utra-Jel. U. S. v. 5 Boxes of Utra-Jel. Decree of condemnation and destruction. (F. D. C. No. 6621. Sample No. 54631-E.)

This product, in addition to being dangerous to health when used as directed, bore statements on its labeling which created the false and misleading impression that it was a safe and effective treatment for the conditions indicated below.

On December 29, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 5 boxes, each containing 4 tubes, of Utra-Jel at Philadelphia, Pa., alleging that the article had been shipped on or about November 29, 1941, from Chicago, Ill., by Pynosol Laboratories, Inc.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a castor oil soap, water, pine oil, and combined iodine.

The article was alleged to be misbranded in that the following statements appearing on its labeling created the false and misleading impression that it was a safe and effective treatment treatment for the conditions hereafter quoted, whereas it was not a safe and effective treatment, but was a dangerous drug: (Tube) "Indicated As An Aid—In Treatment of Minor Infections Of The Cervix And Cervical Canal. As a Uterine Evacuant," (carton) "Indicated as an aid . . . in the treatment of minor infections of the cervix and cervical canal. As a uterine evacuant," (circular) "Cervical Infections And Cervical Erosions (minor) * * * Infections Of The Cervical Canal (Minor) * * * Cystic Cervix * * * As A Uterine Evacuant."

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, as follows: (Circular) "take cotton applicator saturated with UTRAJEL and apply to infected parts. If cervix is extensively eroded, apply 1 cc. to 3 cc. on a wool tampon and place against cervix and leave in place about 12 hours. * * * In addition to the same procedure as outlined in the above paragraph, saturate a small gauze packing with UTRAJEL and insert into the cervical canal, leaving a loose end so that the patient may remove in about 12 hours. * * * Prepare field, gently insert sterilized applicator into the external os and pass it careully along the canal and into the mouth of the uterus remembering the position of the uterus as determined by previous bimanual examination. DOSAGE: 5 cc. to 12 cc. the first month, 15 cc. the second month, 20 cc. to 30 cc. the third month and over. The dosages suggested may be varied slightly depending upon the individual case. In all cases treatment should be administered slowly to eliminate as much the possibility of shock * * *."

On November 10, 1942, an answer to the libel having been filed by Pynosol Laboratories, Inc., and later withdrawn, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS[2]

906. Action to enjoin and restrain interstate shipments of a drug designated as Korjena. U. S. v. Jerome V. Gladke (Korjena Medicine Co.). Permanent injunction granted. (Inj. No. 51.)

On March 1, 1943, the United States attorney for the Western District of New York filed a complaint for an injunction against Jerome V. Gladke, trading as the

[2] See also No. 902.

Korjena Medicine Company, Elmira, N. Y., alleging among other things, that, since 1931, the defendant had been engaged in the business of vending throughout the United States a product known as Korjena, and labeled in part as follows: "Korjena A dependable treatment for the reduction of excessive fat . . . Korjena Medicine Co. Laboratories Elmira, N. Y. U. S. A. This treatment is guaranteed dependable and may be taken with complete confidence. Contents 42 Korjena tablets . . . Active ingredients: phenolphthalein, calcium iodide, sodium choleinate"; that the article contained approximately 1 grain of phenolphthalein, approximately .44 grain calcium iodide, calcium carbonate, and bile salts; and that it was misbranded: (a) In that it was recommended as a dependable, safe, and adequate treatment for the reduction of excess fact, which statement was false and misleading since it was not a dependable, safe, and adequate treatment for the reduction of excess fat. (b) In that its label failed to bear adequate directions for use, since the article was a laxative and the directions which appeared on the label provided for continuous administration, whereas a laxative should not be used continuously. (c) In that its label failed to bear such adequate warnings against use in those pathological conditions wherein use of the article might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users since the article was a laxative and its label failed to warn that a laxative should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present. (d) That its label failed to disclose that frequent or continued use of the article might result in dependence upon laxatives. (e) That its label failed to disclose that, if a skin rash appeared, the use of the article should be discontinued.

The complaint alleged further that on or about December 16, 1941, there was filed in the United States District Court for the Western District of New York an information charging a criminal violation of the Federal Food, Drug, and Cosmetic Act against the defendant for shipment of Korjena in interstate commerce to Pittsburgh, Pa., and that on November 10, 1942, the defendant entered a plea of guilty to count 1 of the information and was fined $200; and that while the criminal information was pending as well as afterwards, the following shipments of Korjena were made by the defendant from Elmira, New York: On October 9, 11, and 27, 1942, and on November 25, 1942, shipments were made to Los Angeles, Calif.; on or about November 27, 1942, some 130 packages were shipped to Tampa, Fla.; on or about December 12, 1942, some 63½ dozen packages were shipped to Philadelphia, Pa.; on or about January 2, 1943, some 711 packages were shipped to Kansas City, Mo.; on or about January 2, 1943, some 11¾ dozen packages were shipped to Erie, Pa.; on or about January 9, 1943, some 11 gross packages were shipped to Detroit, Mich.; on or about January 11, 1943, some 9½ dozen boxes were shipped to Minneapolis, Minn.; and on or about February 19, 1943, some 1 dozen boxes were shipped to St. Paul, Minn. It was also alleged that the only difference in composition between the tablets involved in the criminal case and those in the other shipments listed was that the tablets in the criminal case contained the alkaloid strychnine, in addition to the ingredients above set forth.

The complaint alleged further that on April 10, 1938, the Federal Trade Commission directed the defendant and the Korjena Medicine Company to cease and desist from certain unfair methods of competition in connection with the sale of Korjena tablets, which were advertised as a fat-reducing agent and as a remedy for obesity; and that an action was then pending in the United States District Court for the Western District of New York, instituted on or about October 21, 1941, demanding judgment in the sum of $10,000, and further demanding that this defendant be permanently enjoined from violating the terms of the Federal Trade Commission order to cease and desist; and that the defendant, with full knowledge that the labels constituted a violation of the Act, was selling, and had no intention of discontinuing to sell, Korjena under its objectionable label, but on the contrary was then, and so intended in the future, continuing his business, 80 percent of which consisted in the shipping of the product in interstate commerce; and that, unless restrained by the court, the defendant would continue to introduce and offer for introduction and delivery in interstate commerce the misbranded article, and would in this manner continue to violate, evade, and defeat the purposes of the Act, with injury to the public and to the plaintiff.

On March 1, 1943, an order to show cause and a temporary restraining order were filed.

On March 30, 1943, no appearance, responsive affidavit, or pleading having been filed, the court ordered that the defendant, his agents, servants, and employees, and all other persons in active concert or participation with him, be permanently enjoined and restrained from directly or indirectly introducing and delivering for introduction, and causing to be introduced and delivered for introduction, into interstate commerce the article sold under the name Korjena, as then labeled, in violation of the Federal Food, Drug, and Cosmetic Act.

907. Misbranding of Korjena. U. S. v. Jerome V. Gladke (Korjena Medicine Co.). Plea of guilty. Fine, $200. (F. D. C. No. 5517. Sample Nos. 19250–E, 19370–E.)

On December 16, 1941, the United States attorney for the Western District of New York filed an information against Jerome V. Gladke, trading as the Korjena Medicine Co., Elmira, N. Y., alleging shipment on or about September 18, 1940, and January 10, 1941, from the State of New York into the State of Pennsylvania of a quantity of Korjena which was misbranded.

Analysis of a sample of the article showed that it contained phenolphthalein, compounds of calcium and magnesium, iodides, bile salts, and extracts of plant drugs including a strychnine-bearing drug.

The article was alleged to be misbranded in that the statements, "A Dependable Treatment for the Reduction of Excessive Fat * * * This Treatment is Guaranteed Dependable and may be taken with Complete Confidence * * * Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results * * * This Treatment is dependable in normal conditions * * * All normal cases of excessive weight may confidently follow above directions," borne on the boxes containing the article, were false and misleading since they represented and suggested that the article was a dependable, safe, and adequate treatment for the reduction of excessive fat, whereas it was not a safe, dependable or adequate treatment for such purpose but might produce harmful results. The article was alleged to be misbranded further in that the statement, "Active Ingredients: Phenolphthalein, Calcium Iodide, Sodium Choleinate," borne on the boxes, was false and misleading since the said statement represented and suggested that phenolphthalein, calcium iodide, and sodium choleinate were the only active ingredients, whereas the article contained the active ingredient strychnine in addition to those named; in that it was not designated solely by a name recognized in an official compendium, and was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of strychnine contained in it; in that its label failed to bear adequate directions for use since the directions, "Take 1 tablet after each meal * * * Especially in overweight cases of long standing these tablets should be faithfully taken regularly as directed. Two or three packages are usually required for the best results," were not suitable and appropriate directions for the drug, which was essentially a laxative; in that its labeling did not bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since it was a cathartic or laxative and contained phenolphthalein and should not be used when abdominal pain, nausea, vomiting or other symptoms of appendicitis are present, and frequent or continued use might result in dependence on laxatives, and that it should be discontinued if a skin rash should appear

On December 28, 1942, the defendant having entered a plea of guilty, the court imposed a fine of $200.

908. Adulteration and misbranding of Bullock's System Self Treatment for Sinus and Catarrhal Infection. U. S. v. Henry Spangler (National Laboratories, Inc.). Plea of nolo contendere. Sentence of 180 days in jail conditionally suspended. (F. D. C. No. 7209. Sample No. 50930–E.)

This product, which was packed in a cardboard container, consisted of one can of Bullock's Antiseptic Healing and Cleansing Tonic, one jar of Bullock's Nasal Salve, one box of Bullock's Clear Head Tablets, one vial of Sneeze-It, and one bottle each of King Cold Knockout, Ear Oil, Special Sea Salt, and Bullock's Antiseptic Emollient, and a device which included a nasal atomizer of the common variety, an aluminum can with hose connection for irrigating the sinus, a measuring cup, and a thermometer.